

In The Claims

1 1. (cancelled without prejudice)

1 2. (currently amended) An apparatus comprising:
2 a moldable sheath with sufficient moldability at body temperatures to at least
3 temporarily retain a specific shape selectively imparted to it by a user by bending of the
4 sheath along its length, which specific shape is held without continued inserted
5 presence of a shaping tool in the sheath; and
6 a lumen defined in said moldable sheath.

1 3. (original) The apparatus of claim 2 further comprising a shaping tool for
2 disposition in said lumen of said implanted sheath to impart said specific shape to said
3 sheath.

1 4. (original) The apparatus of claim 3 where said shaping tool is separate from said
2 sheath.

1 5. (original) The apparatus of claim 2 where said shaping tool is incorporated within
2 said sheath.

1 6. (original) The apparatus of claim 2 further comprising a sealing valve coupled to
2 said sheath to seal said lumen.

1 7. (cancelled without prejudice)

1 8. (original) The apparatus of claim 2 where said sheath has at least one portion
2 with a stiffness different than remaining portions of said sheath.

1 9. (original) The apparatus of claim 2 where said sheath has at least one portion
2 with a moldability different than remaining portions of said sheath.

1 10. (original) The apparatus of claim 2 where said sheath is deployed in a body
2 cavity and has at least one portion with a moldability which can be altered at the time of
3 implantation in said body cavity.

1 11 (original) The apparatus of claim 10 where said at least one portion has its
2 moldability altered before said sheath is implanted into said body cavity.

1 12. (original) The apparatus of claim 10 where said at least one portion has its
2 moldability altered after said sheath is implanted into said body cavity.

1 13. – 28. (cancelled without prejudice)

1 29. (allowed) An apparatus comprising:

2 a moldable sheath capable of at least temporarily retaining a specific shape
3 selectively imparted to it by a user by bending of the sheath along its length; and
4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific
6 shape is held without continued inserted presence of said shaping tool in the sheath.

1 30. (allowed) The apparatus of claim 29 where said sheath is characterized by a
2 sufficient moldability so that removal of said shaping tool does not result in any
3 substantial displacement of said sheath from said specific shape.

1 31. (allowed) The apparatus of claim 29 where said sheath has a lumen and where
2 said shaping tool applied to said sheath comprises an elongate shaping tool which is
3 telescopically disposed within said lumen in said sheath.

1 32. (allowed) An apparatus comprising:

2 a moldable sheath capable of at least temporarily retaining a specific shape
3 imparted to it; and

4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific
6 shape is held without continued assistance of said shaping tool,
7 where said shaping tool applied to said sheath comprises a shaping tool applied
8 exteriorly to said sheath and imposing a shaping force thereon.

1 33. (withdrawn) The apparatus of claim 29 further comprising a medical instrument
2 disposed into said body cavity through said sheath.

1 34. (withdrawn) The apparatus of claim 29 where medical instrument comprises a
2 diagnostic instrument.

1 35. (withdrawn) The apparatus of claim 29 where said medical instrument comprises
2 a therapeutic instrument.

1 36. (withdrawn) The apparatus of claim 29 where said medical instrument comprises
2 a cardiac lead for disposition within the coronary sinus of a human heart.

1 37. (allowed) The apparatus of claim 29 where said moldable sheath has at least a
2 portion of changed moldability relative to remaining portions of said sheath.

1 38. (allowed) The apparatus of claim 37 where said portion which changes its
2 moldability while in said body cavity comprises at least a portion of said sheath having a
3 moldability dependant on temperature in which said moldability of said sheath is
4 changed while in said body cavity and exposed to a body cavity temperature elevated
5 above ambient temperature.

1 39. (allowed) An apparatus comprising:

2 a moldable sheath capable of at least temporarily retaining a specific shape
3 imparted to it; and

4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific
6 shape is held without continued assistance of said shaping tool,

7 where said moldable sheath has at least a portion of changed moldability relative
8 to remaining portions of said sheath,

9 where said portion which changes its moldability while in said body cavity
10 comprises at least a portion of said sheath having a moldability dependant on
11 temperature in which said moldability of said sheath is changed while in said body
12 cavity and exposed to a body cavity temperature elevated above ambient temperature,
13 and

14 where said portion which changes its memory shape while in said body cavity
15 comprises at least a portion having a moldability dependant on moisture in which said
16 moldability of said sheath is changed while in said body cavity and exposed to moisture.

1 40. (allowed) The apparatus of claim 37 where said portion of changed moldability
2 has its moldability changed by treating at least a portion of said sheath exterior to said
3 body cavity prior to implanting.

1 41. (allowed) An apparatus comprising:
2 a moldable sheath capable of at least temporarily retaining a specific shape
3 imparted to it; and
4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific
6 shape is held without continued assistance of said shaping tool;
7 where said moldable sheath has at least a portion of changed moldability
8 relative to remaining portions of said sheath,
9 where said portion of changed moldability has its moldability changed by treating
10 at least a portion of said sheath exterior to said body cavity prior to implanting, and
11 where said portion of changed moldability has its moldability changed by
12 exposing at least a portion of said sheath to radiation.

1 42. (withdrawn) The apparatus of claim 40 where said portion of changed moldability
2 has its moldability changed by exposing at least a portion of said sheath to a chemical
3 treatment.

1 43. (withdrawn) The apparatus of claim 29 further comprising a reinforcement
2 selectively disposed on or in said sheath so that a reinforced portion of said sheath has
3 its stiffness increased relative to remaining portions of said sheath.

1 44. (withdrawn) The apparatus of claim 29 further comprising a reinforcement
2 selectively disposed on or in said sheath so that a reinforced portion of said sheath has
3 its ability to retain a specific shape enhanced relative to remaining portions of said
4 sheath.

1 45. (withdrawn) The apparatus of claim 44 where said reinforcement comprises
2 wires, fibers or braid disposed on or on said sheath.

1 46. (withdrawn) The apparatus of claim 43 where said reinforcement comprises a
2 braided reinforcement on or in said sheath.

1 47. (withdrawn) The apparatus of claim 43 where said reinforcement comprises
2 fibers disposed on or in said sheath to provide kink resistance.

1 48. (withdrawn) The apparatus of claim 43 where said reinforcement comprises at
2 least one layer of material at least partially concentrically disposed on or in said sheath.

1 49. (withdrawn) The apparatus of claim 48 where said at least one layer of material
2 at least partially concentrically disposed on or in said sheath comprises at least one
3 cylindrical layer telescopically disposed on or in said sheath.

1 50. (withdrawn) The apparatus of claim 48 where said sheath has a wall with a
2 predetermined thickness and where said at least one layer of material at least partially
3 concentrically disposed on or in said sheath comprises a thickening of said sheath wall.

1 51. (withdrawn) The apparatus of claim 48 where said one layer of material has a
2 moldability different than said sheath.

1 52. (withdrawn) The apparatus of claim 48 where said one layer of material is not
2 moldable like said sheath.

1 53. (allowed) An apparatus comprising:
2 a moldable sheath capable of at least temporarily retaining a specific shape
3 imparted to it; and
4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific
6 shape is held without continued assistance of said shaping tool, where said moldable
7 sheath has a tip portion and where said tip portion is substantially soft and compliant
8 without appreciable moldability.

1 54. (withdrawn) The apparatus of claim 29 where said moldable sheath is splittable,
2 tearable, slittable or peelable.

1 55. (allowed) The apparatus of claim 29 where said moldable sheath is preshaped
2 according to its intended application within said body cavity.

1 56. (allowed) The apparatus of claim 29 where said sheath has a proximal end and
2 further comprising a sealing valve disposed on said proximal end.

1 57. (withdrawn) The apparatus of claim 56 where said sealing valve is splittable,
2 tearable, slittable or peelable.

1 58. (allowed) The apparatus of claim 56 where said sealing valve is integral with
2 said sheath.

1 59. (allowed) The apparatus of claim 56 where said sealing valve is separate from
2 said sheath.

1 60. (allowed) The apparatus of claim 29 further comprising at least one wire
2 disposed in said sheath and usable for deflecting and positioning said sheath.

1 61. (withdrawn) The apparatus of claim 29 further comprising at least one wire
2 disposed in said sheath for providing an electrical conductor therein.

1 62. (withdrawn) The apparatus of claim 61 where said sheath has a distal end and
2 further comprising a diagnostic or therapeutic device at or near said distal end and
3 coupled to said conductor.

1 63. (withdrawn) The apparatus of claim 62 where said diagnostic or therapeutic
2 device comprises an ultrasound imager.

1 64. (withdrawn) The apparatus of claim 29 further comprising a lumen defined in
2 said sheath and at least one inflatable balloon disposed on said sheath coupled to said
3 balloon.

1 65. (withdrawn) The apparatus of claim 64 where said balloon is removable from
2 said sheath.

1 66. (withdrawn) The apparatus of claim 61 further comprising an electrode disposed
2 on or in said sheath and coupled to said conductor.

1 67. (withdrawn) The apparatus of claim 29 further comprising at least one optic fiber
2 disposed in said sheath for providing an optical conductor therein.

1 68. (withdrawn) The apparatus of claim 67 where said sheath has a distal end and
2 further comprising a photonic device disposed in or near said distal end of said sheath
3 and coupled to said optic fiber.

1 69. (withdrawn) The apparatus of claim 29 further comprising a lumen defined in
2 said sheath and a vent communicated to said lumen so that fluid may be infused or
3 suctioned therethrough.

1 70. (allowed) The apparatus of claim 29 where said shaping tool is steerable.

1 71. (allowed) The apparatus of claim 29 where said shaping tool comprises a
2 guidewire.

1 72. (allowed) An apparatus comprising:
2 a moldable sheath capable of at least temporarily retaining a specific shape
3 imparted to it; and
4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific

6 shape is held without continued assistance of said shaping tool, where said shaping tool
7 has a tip portion which is substantially soft and compliant without substantial moldability
8 rendering it nontraumatic.

1 73. (allowed) An apparatus comprising:

2 a moldable sheath capable of at least temporarily retaining a specific shape
3 imparted to it; and

4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific
6 shape is held without continued assistance of said shaping tool, where said shaping tool
7 further comprises at least one lumen defined therethrough and a vent communicated
8 with said lumen.

1 74. (allowed) An apparatus comprising:

2 a moldable sheath capable of at least temporarily retaining a specific shape
3 imparted to it; and

4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific
6 shape is held without continued assistance of said shaping tool, where said shaping tool
7 further comprises a lumen defined therethrough and at least one inflatable balloon
8 communicated with said lumen.

1 75. (allowed) An apparatus comprising:
2 a moldable sheath capable of at least temporarily retaining a specific shape
3 imparted to it; and
4 a shaping tool arranged and configured to be applied to said implanted sheath to
5 impart said specific shape to said sheath while within said body cavity, which specific
6 shape is held without continued assistance of said shaping tool, where said shaping tool
7 further comprises a conductor disposed therethrough and an electrode coupled to said
8 conductor for sensing or delivery of energy from said electrode.

1 76. (withdrawn) An apparatus comprising:
2 a peel-away sheath with sufficient flexibility to be selectively guideable; and
3 a steering or guiding tool to impart a selected shape to said sheath.

1 77. (withdrawn) The apparatus of claim 76 where said peel-away sheath is
2 nonmoldable.

1 78. (withdrawn) The apparatus of claim 76 further comprising a proximal sealing
2 valve coupled to said sheath.

1 79. (withdrawn) The apparatus of claim 76 further comprising a distal diagnostic or
2 therapeutic device coupled to said sheath.

1 80. (withdrawn) The apparatus of claim 76 where said peel-away sheath separates
2 along a longitudinally oriented score line defined in said peel-away sheath.
3

1 81. (withdrawn) An apparatus comprising:
2 a peel-away sheath with sufficient flexibility to be selectively guideable including
3 an elongated flexible body having a proximal end and a distal end; and
4 a peel-away balloon mounted on said flexible body near said distal end thereof.

1 82. (withdrawn) An apparatus comprising:
2 a moldable, peel-away sheath with sufficient flexibility to be selectively guideable;
3 and
4 a dilator telescopically disposable with said sheath so that said sheath may be
5 vascularly implanted.

1 83. - 89. (cancelled without prejudice)

1 90. (allowed) An apparatus comprising:
2 a moldable sheath with sufficient moldability at body temperatures to at least
3 temporarily retain a specific shape imparted to it; and
4 a lumen defined in said moldable sheath, where said sheath has at least one
5 portion with a stiffness different than remaining portions of said sheath wherein the

6 sheath is comprised of a relatively stiffer proximal portion and relatively stiffer distal
7 portion extending to a distal tip with a relatively less stiff intermediate portion
8 therebetween.

1 91. (allowed) An apparatus comprising:
2 a moldable sheath with sufficient moldability at body temperatures to at least
3 temporarily retain a specific shape imparted to it; and
4 a lumen defined in said moldable sheath, where said sheath has at least one
5 portion with a moldability different than remaining portions of said sheath wherein the
6 sheath is comprised of a relatively less moldable proximal portion and relatively less
7 moldable distal portion extending to a distal tip with a relatively more moldable
8 intermediate portion therebetween..

1 92. (withdrawn) The apparatus of claim 9 comprised of a nonmoldable resilient
2 proximal portion and nonmoldable, resilient distal portion extending between 1 to 15 cm
3 from a distal tip with a moldable intermediate portion therebetween.

1 93. (new)¹ A method of using a moldable sheath and using a shaping tool comprising:
2 providing a moldable sheath with sufficient moldability to at least temporarily
3 retain a specific shape selectively imparted to it by a user by bending of the sheath
4 along its length when implanted in a body cavity and by using the shaping tool which is

¹ Derived from claims 1 and 29.

5 arranged and configured to impart the specific shape to the sheath while within the body
6 cavity, which specific shape is held;
7 implanting the sheath within a body cavity;
8 molding the implanted sheath to the specific shape, which specific shape is held
9 without continued assistance of a shaping tool; and
10 utilizing the implanted sheath for a medical procedure.

1 94. (new)² A method of using a moldable sheath and using a shaping tool
2 comprising:
3 providing a moldable sheath capable of at least temporarily retaining a specific
4 shape imparted to it when implanted in a body cavity by a user by bending of the sheath
5 along its length when implanted in a body cavity and by using the shaping tool which is
6 arranged and configured to impart the specific shape to the sheath while within the body
7 cavity, which specific shape is held;
8 implanting the sheath within a body cavity;
9 molding the implanted sheath to the specific shape while within the body cavity,
10 which specific shape is held without continued assistance of a shaping tool; and
11 utilizing the implanted sheath for a medical procedure within the body cavity
12 while the sheath is in the specific shape.

² Derived from claims 13 and 29.

1 95. (new) The method of claim 94 where molding the implanted sheath to a
2 specific shape comprising applying a shaping tool to the sheath to induce the sheath to
3 assume the specific shape.

1 96. (new) The method of claim 94 further comprising removing a shaping tool
2 from the sheath when the sheath is characterized by a sufficient moldability so that
3 removal of the shaping tool does not result in any substantial displacement of the
4 sheath from the specific shape.

1 97. (new) The method of claim 95 where applying a shaping tool to the
2 sheath comprises telescopically disposing the shaping tool within a lumen in the sheath.

1 98. (new) The method of claim 95 where applying a shaping tool to the
2 sheath comprises manipulating the shaping tool to steer the sheath.

1 99. (new) The method of claim 95 where applying a shaping tool to the
2 sheath comprises disposing the shaping tool exteriorly to the sheath and imposing a
3 shaping force thereon.

1 100. (new) The method of claim 94 where utilizing the implanted sheath for a
2 medical procedure comprises disposing a medical instrument in the body cavity.

1 101. (new) The method of claim 94 where utilizing the implanted sheath for a
2 medical procedure comprises performing a diagnostic procedure within the body cavity.

1 102. (new) The method of claim 94 where utilizing the implanted sheath for a
2 medical procedure comprises performing a therapeutic procedure within the body
3 cavity.

1 103. (new) The method of claim 94 where utilizing the implanted sheath for a
2 medical procedure comprises disposing a cardiac lead in the coronary sinus of a human
3 heart.

1 104. (new) The method of claim 94 wherein the sheath has a moldability and
2 further comprising changing the moldability of at least a portion of the sheath.

1 105. (new) The method of claim 94 where providing a moldable sheath
2 comprises providing a sheath having a moldability dependant on temperature and
3 where changing the moldability of the sheath while in the body cavity comprises
4 exposing at least a portion of the sheath to a body cavity temperature elevated above
5 ambient temperature.

1 106. (new) The method of claim 104 where providing a moldable sheath
2 comprises providing a sheath having a moldability dependant on moisture and where
3 changing the moldability of the sheath while in the body cavity comprises exposing at
4 least a portion of the sheath to moisture.

1 107. (new) The method of claim 104 where changing the moldability of the
2 sheath comprises causing a change of the moldability of the sheath by treating at least
3 a portion of the sheath exterior to the body cavity prior to implanting.

1 108. (new) The method of claim 107 where treating the sheath exterior to the
2 body cavity prior to implanting to change its moldability comprises exposing at least a
3 portion of the sheath to radiation.

1 109. (new) The method of claim 107 where treating the sheath exterior to the
2 body cavity prior to implanting to change its moldability comprises exposing at least a
3 portion of the sheath to a chemical treatment.

1 110.³ (new) An apparatus for use with an implanted sheath moldable into a
2 specific shape comprising:

³ Formerly claim 83.

3 a steerable, shaping tool arranged and configured to be applied to the implanted
4 sheath to impart the specific shape to the sheath while within the body cavity, which
5 specific shape is held without continued assistance of the shaping tool; and
6 a proximal steering handle coupled to the steerable, shaping tool.

1 111. (new) The apparatus of claim 110 wherein the steerable, shaping tool is
2 characterized by a selectable shape and comprises at least one wire disposed in the
3 steerable, shaping tool coupled to the proximal steering handle by which wire the shape
4 of the steerable, shaping tool is controlled.

1 112. (new) The apparatus of claim 110 further comprising an inflatable balloon
2 coupled to the steerable, shaping tool.

1 113. (new) The apparatus of claim 110 wherein the steerable, shaping tool is a
2 steerable catheter.

1 114. (new) The apparatus of claim 113 wherein the steerable catheter further
2 comprises at least one electrode.

1 115. (new) The apparatus of claim 113 wherein the steerable catheter further
2 comprises at least one lumen and an communicating orifice allowing communication of
3 fluid through the lumen and orifice.

1 116. (new) The apparatus of claim 113 further comprising an inflatable balloon
2 coupled to the catheter.